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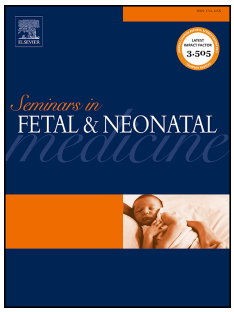


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**Designing a trial for neonatal seizure treatment**

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SUMMARY

Neonatal seizures are widely considered a neurological emergency with a need for prompt treatment, yet they are known to present a highly elusive target for bedside clinicians. Recent studies have suggested that the design of neonatal seizure treatment trial design will profoundly influence the sample size, which may readily increase to hundreds or even thousands, while the achieved effect size may diminish to clinical irrelevance. The self-limiting and rapidly resolving nature of neonatal seizures diminishes the achievable treatment effect every hour after seizure onset and measured effects may be confused with spontaneous resolution, precluding the value of many observational studies. The large individual variability in seizure occurrence over time and between etiologies challenges group comparisons, while the absence of clinical signs mandates quantification of seizure occurrence with continuous multi-channel EEG monitoring. A biologically sound approach that views neonatal seizures as a functional cot-side biomarker rather than an object to treat can overcome these challenges.

*Keywords:*

Status epilepticus

Antiepileptic drug

Randomized control trial

Episodic illness

Migraine

Infection